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10/500,082	06/24/2004	Shuichi Kitamura	542-012.010	5847

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EXAMINER

BERNSHTEYN, MICHAEL

ART UNIT	PAPER NUMBER
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1796

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,082

Applicant(s)

KITAMURA ET AL.

Examiner

Michael M. Bernshteyn

Art Unit

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9-11,13-17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-11,13-17 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/31/2007.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 20080108.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action follows a response filed on October 31, 2007. Claim 1 has been amended; claims 20 and 21 have been added; no claims have been cancelled.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007 has been entered.
3. In view of the amendment(s) and remarks, the rejection of claims 1, 3-7, 9-11, 13-17 and 19 under 35 U.S.C. 103(a) as being unpatentable over Nishiguchi et al. (JP 09-324096) in view of Fujiwara et al. (EP 1 251 147 A1) has been withdrawn.
4. Applicant's arguments with respect to claims 1, 3-7, 9-11, 13-17 and 19 have been considered but are moot in view of the new ground(s) of rejection.
5. Claims 1, 3-7, 9-11, 13-17 and 19-21 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 20 recites "The film of claim 1, wherein the polyvinyl alcohol resin (A) is not modified". The specification does not contain any definition of modified polyvinyl alcohol resin (A) in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 21 recites "The film of claim 3, wherein the at least two kinds of polyvinyl alcohol resin (A) are not modified". The specification does not contain any definition of at least two kinds of modified polyvinyl alcohol resin (A) in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

7. Claims 3-7, 11, 13-17 and 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "The film of claim 1, which is prepared by forming a film from a resin composition [I] containing at least two kinds of polyvinyl alcohol resins (A) having different degrees of hydrolysis" while the newly amended claim 1 recites "A polyvinyl

alcohol film which is formed from a polyvinyl alcohol resin (A)...wherein the polyvinyl alcohol resin (A) has a degree of hydrolysis from the range of 55 to 100% by mole".

Therefore, it is not clear how many different kinds of polyvinyl alcohol resins (A) should be in the composition: one resin (A) according claim 1, or at least two resins (A) according claim 3?

Claim Rejections - 35 USC § 103

8. The text of this section of Title 35 U.S.C. not included in this action can be found in a prior Office Action.

9. Claims 1, 3-6, 9-11, 13-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishiguchi et al. (JP 09-324096) in view of Hirata et al. (JP 2001-316491).

With regard to the limitations of claims 1, 3-6 and 11, Nishiguchi discloses a composition comprises a modified PVA resin having anionic groups (preferably **carboxyl and/or sulfo groups**) preferably in the amount of 2.0-40.0-mol% and a PVA resin having a degree of saponification of 70-99% and a degree of polymerization 200-8,000. The modified PVA resin having carboxylic groups is produced by Michael addition reaction with acrylonitrile or acrylamide and partly or fully hydrolyzing the reaction product, wherein the weight ratio of A/B is from 95:5 to 5:95, which is within the claimed range (abstract). Example 1 discloses a film formed from a composition comprising a mixture of 35 parts of a modified PVA having saponification degree of 96.3%, and 65 parts of a modified PVA having saponification degree of 71.1%. This film

has mechanical strength, alkali-resistance, hygroscopic and crack resistance and has dissolution rate; it is suitable to encapsulate chemical products (Table 1, page 4, [0038]-[0040]).

Nishiguchi does not disclose that polyvinyl alcohol composition contains 0.1 to 50 parts by weight of trimethylolpropane as plasticizer (C).

With regard to the limitation of claim 1, Hirata discloses a polyvinyl alcohol based film containing a plasticizer such as glycerol, diglycerol, diethylene glycol, triethylene glycol, propylene glycol, **trimethylolpropane**, etc. These may be used singly or in combination of at least two (page 4, [0026]). The amount of the plasticizer to be mixed is preferably from 1 to 30 parts by weight per 100 parts by weight of the PVA, which is clearly within the claimed range (page 4, [0027]).

Both references are analogous art because they are from the same field of endeavor concerning water-soluble film comprises a polyvinyl alcohol and a plasticizer.

Therefore, all of the above plasticizers are functional equivalents and can be substituted by each other. Thus, Hirata recognizes the equivalency of glycerol, diglycerol or ethylene glycol used by Hishiguchi and trimethylolpropane as a plasticizer for a polyvinyl alcohol resin. In the instant case the substitution of equivalents solvents requires no express motivation, as long as the prior art recognize equivalency, *In re Fount*, 213 USPQ 532 (CCPA 1982); *In re Siebentritt*, 152 USPQ 618 (CCPA 1967); *Graver Tank & Mfg. Co. Inc. V. Linde Air Products Co.* 85 USPQ 328 (USSC 1950), and a person skilled in the art would have found obvious to substitute glycerol, diglycerol or ethylene glycol used by Hishiguchi for trimethylolpropane of Hirata in the

adjusted amount based on their recognized equivalency and with the reasonable expectation of success, and thus to arrive at the subject matter of instant claim 1.

With regard to a ratio of storage modulus and a glass temperature instantly claimed in claim 1, the combined teaching of Nishiguchi and Hirata is silent about it. However, in view of substantially identical polyvinyl alcohol composition between Nishiguchi and Hirata and instant claim 1 (exactly the same polymerized monomers, degrees of hydrolysis, the difference in degree of hydrolysis, plasticizer and its amount, substantially identical method of the preparation of the final composition), it is the examiner position that Nishiguchi and Hirata's polyvinyl alcohol composition possesses these properties. Since the USPTO does not have equipment to do the analytical test, the burden is now shifted to the applicant to prove otherwise. *In re Best* 195 USPQ 430, (CCPA 1977).

With regard to the limitations of claims 9-10, 13-17 and 19, Nishiguchi discloses the usage of ethylene glycol, glycerol or diglycelol as plasticizers, and low-molecular weight polyethylene glycol, coloring agent, an alkaline substance, agricultural chemicals, etc. (page 3, [0026]-[0027]). All of the above compounds can be considered as chemicals.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nishiguchi'096 and Hirata et al. as applied to claims 1, 3-6, 11-17 and 19 above and further in view of Nishiguchi et al. (JP 10-060207).

With regard to the limitations of claim 7, the combined teaching of Nishiguchi'096 and Hirata discloses that further the components can be mixed with fine particles

(JP'096, page 3, [0022]), but it does not disclose that polyvinyl alcohol film further contains inorganic filler (B) having an average particle size of 1 to 10 μm .

Nishiguchi'207 discloses a water-soluble film comprises (A) a modified polyvinyl alcohol and (B) preferably 2-20 wt. % (based on the component A) of fine powder such as clay which has less or equal to 150 μm average particle diameter (abstract). Such class of insoluble or poorly soluble impalpable powder can include clay, kaolin, an aluminum hydroxide, a calcium carbonate, a titanium hydroxide, etc. (page 3, [0025]).

The references are analogous art because they are from the same field of endeavor concerning water-soluble film compositions comprising polyvinyl alcohol and additional ingredients.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate inorganic fine powder having an average particle diameter less or equal to 150 μm as taught by Nishiguchi'207 into the combined Nishiguchi'096 and Hirata's polyvinyl alcohol film composition because all of such impalpable powder prevent the stickiness accompanying moisture absorption and its effect on film physical properties is suppressed (JP'207, page 3, [0026]), and thus to arrive at the subject matter of claim 7.

Thus, the combination of Nishiguchi's references and Hirata renders all instant claims *prima facie* obvious in view of absent of unexpected results commensurate in scope of claims.

Response to Amendment

11. The Declaration under 37 CFR 1.132 filed on October 31, 2007 is insufficient to overcome the rejection of claims 1, 3-7, 9-11, 13-17 and 19 under 35 U.S.C. 103(a) based upon Nishiguchi et al. (JP 09-324096) in view of Fujiwara et al. (EP 1 251 147 A1) as set forth in the last Office action because: the showing is not commensurate in scope with the claims.

Claim 1 recites "A polyvinyl alcohol film which is formed from a polyvinyl alcohol resin (A)...wherein the polyvinyl alcohol resin (A) has a degree of hydrolysis from the range of 55 to 100% by mole". It is clear from the limitations of the claim that the polyvinyl alcohol film is formed from the only polyvinyl alcohol resin (A) having the definite degree of hydrolyses, while the Declaration describes the experiments of forming a film from a resin composition containing at least two kinds of polyvinyl alcohol resins (A) having different degrees of hydrolysis, which is out of the scope of the amended claim 1.

12. In response to Applicants argument that the Applicant submits additional evidence showing that both glass transition temperature and α/β ratio of the polyvinyl alcohol film disclosed in Nishiguchi is out of the range of the present invention (page 7, the last paragraph), it is well settled that the Applicants have to use the closest prior art to run a consecutive "back-to-back" test to show unexpected results, if any. "Showing unexpected results over one of two equally close prior art references will not rebut *prima facie* obviousness unless the teachings of the prior art references are sufficiently similar to each other that the testing of one showing unexpected results would provide the

same information as to the other". *In re Johnson*, 747 F.2d 1456, 1461, 223 USPQ 1260, 1264 (Fed. Cir. 1984).

Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument."). See also *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991). See MPEP 716.01(c).

Response to Arguments

13. Applicants traverse the rejection of claims 1, 3-7, 9-11, 13-17 and 19 under 35 U.S.C. 103(a) as being unpatentable over Nishiguchi et al. (JP 09-324096) in view of Fujiwara et al. (EP 1 251 147 A1). Applicant's arguments have been fully considered but they are not persuasive.

14. As to Applicants arguments that the plasticizer trimethylolpropane as claimed is essential in achieving a T_g of not more than 20°C in the PVA film of the present invention, and the lower T_g thus resulted makes the PVA film of the present invention different from the PVA film of JP-096 (page 6), it is noted that current Office Action (paragraph 9) contains the rejection of amended claim 1 with all new limitations.

15. Regarding to Applicants arguments that the PVA films of the Examples 1, 2 and 3 in the specification contain 20 parts by weight of trimethylolpropane per 100 parts by weight of the total of the PVA, and the polyvinyl alcohol resin (A) has a degree of hydrolysis from the range of 55 to 100% by mole (page 6, the last paragraph), it is noted that the above mentioned examples describe the films being obtained from a resin composition containing at least two kinds of polyvinyl alcohol resins (A) having different degrees of hydrolysis, which is out of the scope of the amended claim 1.

16. In response to Applicants argument that the elongation values of the examples 1, 2 and 3 of the instant application indicate that the glass transition temperatures of the samples must be higher than the temperature under which the elongation was measured (page 7, 1st paragraph), it is noted that in view of substantially identical polyvinyl alcohol composition between Nishiguchi and Hirata and the amended claim 1 (exactly the same polymerized monomers, plasticizer and its amount, substantially identical method of the preparation of the final composition), it is the examiner position that Nishiguchi and Hirata's polyvinyl alcohol composition possesses these properties. Since the USPTO does not have equipment to do the analytical test, the burden is now shifted to the applicant to prove otherwise. **In re Best** 195 USPQ 430, (CCPA 1977).

17. In response to Applicants argument that as shown in Fig. 118 (document "POVAL", glycerol contents vs. second order transition temperature), when 3 weight % of glycerol as plasticizer is added, Tg of the general polyvinyl alcohol remains around 50°C, which is much higher than the Tg of the polyvinyl alcohol in the present invention (page 7, 4th paragraph), it is well settled that "an applied reference may be relied upon for all that it would have reasonably suggested to one of ordinary skill in the art, including not only preferred embodiment, but less preferred and even non preferred". *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael M. Bernshteyn whose telephone number is 571-272-2411. The examiner can normally be reached on M-Th 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

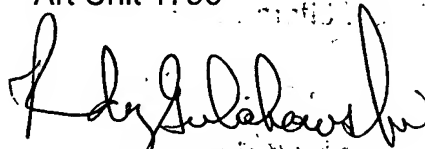
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MB
01/14/2008

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